K112981

JAN 25 2012

510k Premarket Notification Summary

Date: September 30, 2011

Submitted by:

Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940
Ph: 321-259-6862
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Attn: Noel Downey

Classification Name: System, Radiation Therapy, Charged-Particle, Medical

Common Name: Ionization Chamber

Proprietary Name: Sun 125c Ionization Chamber

Establishment Registration Number: 1038814

Classification: Class II, Classification LHN

Performance Standards: To our knowledge, none have been established

Substantial Equivalence: This instrument is similar in function to PTW 31006 – 1.015cc Pinpoint Ionization Chamber, **K972212**.

Description and Use:

The Sun Nuclear model 1041 "SUN125c" is a waterproof, fully-guarded, cylindrical "thimble" type ionization chamber constructed primarily of ABS plastic. The chamber is mounted to a low-noise, high impedance triaxial cable which is terminated with either a bayonet (BNC) or threaded triaxial (TNC) connector. The ionization volume of the chamber is 0.125 cc, which is appropriate for beam scanning and absolute dose measurements. This active volume is vented to the atmosphere through the cable sheath, allowing for conventional air density corrections.

Intended Use:

The Ionization Chamber model 1041 is intended for the purpose of calibrating and measuring the ionizing radiation output from medical radiation therapy machines. This includes beam scanning as well as absolute dose calibration.

Similarities and Differences between SNC Sun 125c Ionization Chamber and PTW 31006:

Similarities with Marketed Devices:

Both devices work on the same principles of:

- Application of an externally generated voltage across the ionization volume.
- Collection of ion current on a central electrode, connected through a high impedance cable to the measurement electrometer.
- Achieve a dosimetric response close to that of water
- Atmospheric communication that allows air density correction
- Waterproof ionization chamber

Differences with Marketed Devices

The Sun125c has a larger active measurement volume than the predicate device.

Safety and Effectiveness

The indications for use, design, materials, manufacturing, and specifications of the Sun125c ionization chamber does not raise any issues with regards to safety and effectiveness.

Comparison to Predicate device:

Sun Nuclear Corporation considers the Sun125c ionization chamber equivalent in all respects to the predicate devices for radiation therapy beam data acquisition.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 25 2012

Ms. Noel Downey
Project Materials Manager
Sun Nuclear Corporation
425 Pineda Court
MELBOURNE FL 32940

Re: K112981
Trade/Device Name: 1041-Scanning Ionization Chamber
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: September 30, 2011
Received: October 6, 2011

Dear Ms. Downey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K112981

Device Name: 1041- Scanning Ionization Chamber

Indications for Use:

The Ionization Chamber model 1041 is intended for the purpose of calibrating and measuring the ionizing radiation output from medical radiation therapy machines. This includes beam scanning as well as absolute dose calibration.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

Mary S Patel

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112981